REMARKS

The Office Action has rejected Claims 38, 40-48, 54-56, 59, 60 and 63-73 under 35 U.S.C. § 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 40 is also rejected under 35 U.S.C. § 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Moreover, claim 59 is rejected35 U.S.C. § 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action has also rejected claims 38, 43, 44, 46, 47, 54, 55,59, 60, 63-66 and 71-73 under 35 U.S.C. § 102(b) as defining subject matter which is allegedly anticipated by the teachings of U.S. Patent No. 6,126,969 to Shah et al. Claims 38, 43, 54-56, 59, 60 and 71-73 are rejected under 35 U.S.C. § 102(b) as defining subject matter which is allegedly anticipated by the teachings in U.S. Patent No. 6,387,403 to Seroff et al. (Seroff et al.). Further, the Office Action has rejected claims 38, 43, 44, 46, 47, 54-56, 59, 60, 63-66 and 71-73 under 35 U.S.C. § 103 as defining subject matter which is allegedly rendered obvious by the teachings in Shah et al. Moreover, claims 38, 40-44, 46-48, 54-56,59, 60, and 63-73 are rejected under 35 U.S.C. § 103(a) as defining subject matter which is allegedly rendered obvious by the teachings in Shah et al. and further in view of U.S. Patent No. 6,416,786 to Mulye et al. ("Mulye et al."). In addition,, claims 38, 43, 44, 46-48, 54-56, 59, 60 and 63-73 are rejected under 35 U.S.C. § 103(a) as defining subject matter which is allegedly rendered obvious by the teachings of Shah et al. and further in view of the teachings in an article by Tobyn et al. in Intl. J. Pharm. 1998 169, 183-194 ("Tobyn et al."). Furthermore, Claims 38, 43-47,54-56, 59, 60, 63-66 and 71-73 are rejected under 35 U.S.C. § 103 (a) as defining subject matter which is allegedly unpatentable over the teachings in Shah et al. in view

of the teaching in U.S. Patent No. 6,340,475 to Shell et al. ("Shell et al."). Moreover, Claims 38, 40-47, 54-56, 59, 60 and 63-66 and 71-73 are rejected under 35 U.S.C. § 103 as defining subject matter which is rendered obvious by the teachings of Seroff et al. and further in view of the teachings of Shell et al. Finally, claims 38, 40-48, 54-56, 59, 60 and 63-73 are rejected under 35 U.S.C. §103(a) for defining subject matter which is allegedly rendered obvious by the teachings in Seroff et al. and Shell et al. and further in view of the teachings in Tobyn et al.

Applicant has amended the claims, which, when considered with the comments hereinbelow, are deemed to place the present application in condition for allowance. Favorable consideration is respectfully requested.

In particular, applicant has amended Claim 38 to place the term "solid" before the term "oral form" recited in claim 1. Support for the term solid is found throughout the specification, for example in Paragraph 21 and original claim 1. Moreover, the mixture in Claim 1 has been amended to recite that it is homogenous. Support thereof is found in Paragraphs 63-66 of the instant specification. Claim 38 has further been amended to recite that the water insoluble or partially water insoluble cellulose in combination with maltodextrin further effect the release of the drug from said pharmaceutical composition. Support is found in Paragraph 52. Finally claim 38 as well as claims 43, 44, 54, 55, 56, 63, 64, 65, and 66 have been amended by identifying the cellulose recited therein as water insoluble or partially water insoluble cellulose, as described throughout the instant specification and identified as such in original claim 1. Further, the claim makes clear that the weight ratio refers to the ratio by weight of the total amount of water insoluble or partially insoluble cellulose to maltodextrin. Support is found in paragraphs 48 and 49 of the present application. Claims 40, 59 and 60 have been amended to be in conformance with the language used in claim 38.

No new matter has been added to the application.

Pursuant to the rejection of claims 38, 40-48,54-56,59,60 and 63-73 under 35 U.S.C. §112, second paragraph, the Office action alleges that it is unclear whether the water insoluble or partly water insoluble cellulose is included in the weight ratio. As amended, it is clear that the weight ratio refers to the total amount of water insoluble or partially water insoluble cellulose to maltodextrin in the core. Therefore, the metes and bounds of the claim are clearly understood to one of ordinary skill in the art. Thus, for the reasons provided, this rejection is obviated; withdrawal thereof is respectfully requested.

Pursuant to the rejection of claim 40 under 35 U.S.C. § 112, second paragraph, the Office Action alleges that there is no antecedent basis in claim 38 for the term "sustained release polymer" recited in claim 40. Claim 38 was amended to change the term "sustained release carrier" to --sustained release polymer--, thus providing the antecedent basis for the term in claim 38. Thus, this rejection is obviated; withdrawal thereof is respectfully requested.

The Office Action has rejected claim 59 under 35 U.S.C. § 112, second paragraph, alleging that there is no antecedent basis for the term "solid unit dosage oral form". Claim 59 was amended to recite the same term as recited in claim 38, upon which it depends. Therefore, for the reasons provided, this rejection is obviated; withdrawal thereof is respectfully requested.

Pursuant to the rejection of Claims 38, 43, 44, 46, 47, 54, 55, 59, 60, 63-65 and 71-73 the Office Action cites Shah et al.

The present invention is directed to, inter alia, a sustained release pharmaceutical composition in solid oral dosage form having a core, said sustained release pharmaceutical composition comprising, in the core thereof, a homogeneous mixture comprising a

pharmaceutically effective amount of a drug, a sustained release carrier in an effective amount to retard the release of the drug from said composition when placed in an aqueous system, a water insoluble or partially water insoluble cellulose, maltodextrin and optionally a lubricating effective amount of a lubricant, wherein the weight ratio of the total amount of said water insoluble or partially water insoluble cellulose to maltodextrin ranges from about 50:1 to about 1:50 and wherein said water insoluble or partially water insoluble cellulose in combination with maltodextrin further effect the release of the drug from said pharmaceutical composition. As described in the specification, the sustained release carrier influences the release of the drug from the formulation. However, this release can be fine tuned by the additional combination of maltodextrin and the water insoluble or partially water insoluble cellulose, such as microcrystalline cellulose, silicified microcrystalline cellulose, and the like. As noted by Applicant in Paragraph 46 of the instant application, the presence of the excipient, the water insoluble or partially water insoluble cellulose, had made it difficult to formulate controlled release tablets because they cause the disintegration of the tablet when in contact with an aqueous solution, causing the release of the medicament to be more rapid than desired. However, the inventor has found that this effect can be counteracted by the addition of maltodextrin. Thus, the present invention requires the interaction of maltodextrin with the water insoluble or partially water insoluble cellulose and the interaction of both with the drug. Further, the sustained release polymer generally controls the release of the drug from the pharmaceutical composition. Thus, all four of these components need to be in the core so that they can interact directly.

If the maltodextrin were not present in the core, it could not form a homogenous mixture, as defined herein, with the water insoluble cellulose or the partially water insoluble

cellulose, e.g., it could not interact with the water insoluble cellulose or partially water insoluble cellulose and counteract its effect in accelerating the release of the drug in the formulation. The cited prior art, alone or in combination, do not teach, disclose or suggest the presence of all four components in the core. None of the references contain all four of these components in a homogeneous mixture, as defined in Paragraph 64 herein. But, more importantly, the cited art do not teach, disclose or suggest that the maltodextrin and water insoluble or partially water insoluble cellulose in combination fine tune the release of the drug controlled by the sustained release polymer.

Shah et al. disclose an orally administrable combination immediate release/sustained release tablet comprising a compressed homogenous mixture of uncoated particles of an active pharmaceutical ingredient and particles of that same ingredient which are coated with a polymer material which is pH independent, so that the sustained release dosage form provides controlled release. The coated particles are present in an amount which is effective to provide a sustained therapeutic effect and the uncoated particles are present in an amount which is effective to provide an immediate therapeutic effect. In an embodiment, the active pharmaceutical ingredient is acetaminophen and the coated acetaminophen is combined with uncoated acetaminophen to provide a combination immediate release/sustained release dosage form. However, to maintain the immediate release/sustained release dosage form, the coated acetaminophen and uncoated acetaminophen must be separate and discrete, otherwise the formulation in Shah et al. would not have separate immediate release and sustained release units.

The Office Action refers to the formulations in Table 1 and Table 2 of Shah, alleging that Shah et al. disclose the present composition. However, Tables 1 and 2 refer to the composition described in Examples 1 and 2, respectively in Shah et al. Example 1 discloses that

microcrystalline cellulose is mixed with a sustained release coated acetaminophen containing acetaminophen, isononylphenyl polyoxyethylene glycol ethers, methacrylate ester copolymer and talc, and then acetaminophen and microcrystalline cellulose are mixed with crosslinked PVP and uncoated acetaminophen. It further teaches that the uncoated acetaminophen is comprised primarily of acetaminophen and contains minor amounts of maltodextrin and PVP. Thus, in Example 1 the microcrystalline cellulose is present with sustained release coated acetaminophen, while the maltodextrin is present in a different discrete, but separate units, with the immediate release acetaminophen. Thus, the maltodextrin in Example 1 is not a part of a homogeneous mixture with the microcrystalline cellulose, as claimed, and therefore cannot interact with the microcrystalline cellulose in combination and cannot further control the release of the drug which is unlike the present invention.

Example 2 indicates that the tablet is prepared in accordance with the procedure in Example 1. Thus, in Example 2, the microcrystalline cellulose cannot interact with the maltodextrin and in combination further control the release of the drug, as claimed.

Case law has held that anticipation requires a single source to contain all of the elements in the claim. Hybritech Inc. v. Monoclonal Antibodies Inc., 802 F2d 1367, 1379, 231 USPQ 81, 90 (Fed Cir 1986). Further, the single source must disclose all of the claimed elements arranged as in the claims. Therasense Inc. v. Becton, Dickinson & Co. ,593 F3d 1325, _____, 93 USPQ 2d 1481, 1485 (Fed. Cir. 2010). A claim cannot be treated as more catalogs of parts. Id.

Here, Shah et al. do not arrange the elements as in the claim. The claim requires that the drug, the water insoluble cellulose or partially water insoluble cellulose, sustained release carrier and maltodextrin to be present and mixed together in the core of the tablet and that

the maltodextrin and the water insoluble or partially water insoluble cellulose in combination further control the release of the drug. However, in Shah et al., the microcrystalline cellulose and the maltodextrin do not interact but are present in discrete, but separate units. In other words, the microcrystalline cellulose and maltodextrin are not part of a homogenous mixture. That is, in Shah et al., maltodextrin is not part of a sustained release formulation. In Shah et al., the drug, the microcrystalline cellulose, maltodextrin are not all present in the a sustained release formulation and thus the maltodextrin and microcrystalline cellulose cannot, in combination, act to control and fine-tune the release of the drug , in contrast to what is claimed by the present invention. Since all of the elements in Shah et al. are not arranged as in the claim, Shah et al. do not anticipate the present invention. Therefore, this rejection is obviated; withdrawal thereof is respectfully requested.

Pursuant to the rejection of Claims 38, 43, 54-56, 59, 60 and 71-73 under 35 U.S.C. § 102(b), the Office Action cites Seroff et al.

Seroff et al. disclose an osmotic dosage form adapted to release reboxetine at a uniform rate comprising

(a) a semipermeable membrane defining an internal compartment;

(b) an osmotic composition component comprising reboxetine and a carbohydrate within the internal compartment and

(c) a delivery orifice formed or formable in the semipermeable membrane through which the roboxetine is delivered.

The Office Action refers to Figure 2 and Example 4B. Figure 2 represent a bilayered core having two compartments. In Example 4B, the drug layer combines reboxetine, maltodextrin and stearic acid, and another layer, identified as the push layer, contains

hydroxypropylmethylcellulose, which is hydrophilic and soluble in water and the barrier layer contains ethyl cellulose and stearic acid. Thus, Seroff et al. do not contain a water insoluble or partially water insoluble cellulose in the same layer as the maltodextrin. Moreover, the sustained release polymer, the drug, the water insoluble or partially water insoluble cellulose such as ethyl cellulose and the maltodextrin are in different layers. Since in Seroff et al., the maltodextrin and the water insoluble or partially water insoluble cellulose are in different layers, they cannot be part of a homogenous mixture and they cannot interact with each other so that together they cannot further control the release of the drug. Thus, Seroff et al. do not teach disclose or suggest the arrangement of elements, as claimed. Therefore, Seroff et al. do not anticipate the present invention. Consequently, this rejection is obviated; withdrawal thereof is respectfully requested.

Pursuant to the rejection of Claim 38, 43, 44, 46, 47, 54-56, 59, 60, 63-66 and 71-71 under 35 U.S.C. § 103, the Office Action cites Shah et al.

The Office Action refers to the formulations in Table 1 and 2 of Shah et al. alleging that the compositions therein render obvious the present invention.

Applicant respectfully disagrees. Tables 1 and 2 of Shah et al. refer to the composition described in Examples 1 and 2, respectively. The composition of Table 1 consists of two discrete dosage units, one comprised of an immediate release acetaminophen and the other being a sustained release acetaminophen. The immediate release portion contains drug, maltodextrin and PVP, while the sustained release unit contains drug, the sustained release carrier, and is mixed with microcrystalline cellulose. Thus, the maltodextrin and microcrystalline cellulose are not part of a homogenous mixture. In other words, they are both not present in the same unit, but are present in different units, one in the sustained release portion, the other in the immediate release portion, which are separate and discrete in Shah et al.

Therefore, in Shah et al., the maltodextrin and the water insoluble or partially water insoluble cellulose cannot interact with each other so that they cannot act together to further control the release of the drug, as claimed. In other words, in Shah et al., the drug, the sustained release carrier, and the cellulose which is partly or fully insoluble in water and maltodextrin are not arranged so that they can interact with one another, i.e., in Shah et al., they are not all present together as part of a homogenous mixture to interact with one another in the same unit, as claimed. Shah et al. do not teach, disclose or even suggest the presence of all of these ingredients together in a homogeneous mixture, as claimed. Thus, Shah et al. do not teach, disclose or suggest the present invention. Therefore, this rejection under 35 U.S.C. § 103 is obviated; withdrawal thereof is respectfully requested.

Pursuant to the rejection of Claims 38, 40-44, 46-48, 54-56, 59, 60, 63-66 and 71-73, the Office Action cites Shah et al. and Mulye et al.

Applicant reiterates its comments with respect to Shah et al. As described hereinabove, Shah et al. do not teach, disclose or suggest the maltodextrin, the drug, the sustained release polymer and the water insoluble or partially insoluble cellulose present in a homogenous mixture in the same controlled release formulation, as claimed.

Mulye et al. do not overcome this deficiency.

Mulye et al. disclose a solid sustained release pharmaceutical tablet for administering to a host, comprising a therapeutically effective amount of a pharmaceutically active ingredient and a sustained release carrier, the sustained release carrier comprising (a) a hydrocolloid selected from the group consisting of xanthan gum, guar gum and alginic acid or a pharmaceutically acceptable salt thereof and (b) a cellulose ether, said hydrocolloid and cellulose ether being present in synergistic effective amounts to retard the release of the pharmaceutically

active ingredient. The Office Action alleges that Mulye et al. disclose therein a filler such as microcrystalline cellulose, referring to Column 7, Lines 3-17 of Mulye et al.

The Office Action alleges that Shah et al. do not disclose xanthan gum in conjunction with a cellulose ether as the sustained release material or the use of silicified MCC. It cites Mulye for its teaching of a sustained release component comprising xanthan gum and a cellulose ether. Even if the sustained release carrier in the composition of Shah et al. were replaced with xanthan gum and cellulose ether, and the microcrystalline cellulose in Shah et al. were replaced with silicified MCC, the combination still does not teach, disclose or suggest the present invention. As indicated hereinabove, in Shah et al., the maltodextrin is not part of a homogenous mixture with the microcrystalline cellulose, sustained release carrier and drug; thus the maltodextrin is in a different portion of the composition which is separate and discrete from the sustained release portion comprised of the microcrystalline cellulose, the sustained release carrier and drug. More specifically, in Shah et al., the maltodextrin is present with the uncoated acetaminophen, while the microcrystalline cellulose, the sustained release carrier and drug are present in the sustained release portion. Thus, even if the sustained release carrier of Shah et al. were substituted with xanthan gum and cellulose ether, the maltodextrin would still not be in a sustained release formulation with the microcrystalline cellulose and the sustained release carrier and the drug. Thus, the combination would suggest that the maltodextrin would be in a different release formulation from the one containing microcrystalline cellulose. Consequently, the combination would suggest that the maltodextrin, for example, could not interact with the microcrystalline cellulose to further control the release of the drug. This is in contrast with the present invention, where the maltodextrin and the water insoluble or partially water insoluble cellulose interact with one another to further control the release of the drug.

Therefore, the combination of Shah et al. and Mulye does not teach, disclose or suggest the present invention.

Thus, for the reasons provided, this rejection is obviated; withdrawal thereof is respectfully requested.

Pursuant to the rejection of Claims 38, 43, 44, 46-48, 54-56, 59, 60, 63- 73 under 35 U.S.C. § 103, the Office Action cites Shah et al. and Tobyn et al.

Applicant reiterates its comments hereinabove with respect to Shah et al., the contents of which are incorporated by reference.

Tobyn et al. teach that there is no chemical or polymorphic difference between a sample of MCC and SMCC, indicating that the silicification process produces a material which is chemically and physically very similar to standard MCC.

Tobyn et al. do not overcome the deficiencies of Shah et al. described hereinabove. As described hereinabove, Shah et al. suggest the presence of maltodextrin in a different release formulation from the microcrystalline cellulose, drug and sustained release carrier, the latter components being in the sustained release unit. In Shah et al, there is no interaction of the water insoluble or partially water insoluble cellulose with the maltodextrin, and as Shah et al. do not teach, disclose or suggest that these components are part of a homogenous mixture. Therefore in Shah et al., they cannot in combination further control the release of the drug. Since Tobyn et al. merely disclose that there is no discernible chemical or polymorphic difference between silicified microcrystalline cellulose and standard grade microcrystalline cellulose, Tobyn et al. do not address the deficiency described hereinabove. Moreover, the combination would suggest SMCC, the drug and the hydrophilic carrier in the sustained release unit, with the immediate release unit comprised of the drug and the maltodextrin mixed together.

Thus, the applicant respectfully submits that the combination of the two references suggests a composition wherein the maltodextrin is not in the same unit as the drug, the water insoluble or partially water insoluble cellulose, and the sustained release carrier. Furthermore, the combination does not teach, disclose or suggest maltodextrin interacting with the drug and the water insoluble or partially water soluble cellulose. The combination does not teach, disclose or suggest a matrix where the active component, the water insoluble or partially water insoluble cellulose, maltodextrin and a sustained release carrier are present in a homogenous mixture in the controlled release formulation, as presently claimed nor does the combination teach or suggest that the water insoluble or partially water insoluble cellulose interact with each other so that in combination, they further effect the control of the drug, as claimed. Thus, this rejection is obviated, withdrawal thereof is respectfully requested.

Pursuant to the rejection of Claims 38, 43-47, 54-56, 59, 60, 63-66 and 71-73, the Office Action cite Shah et al. and further in view of Shell et al.

Applicant reiterates the comments hereinabove with respect to Shah et al., the contents of which are incorporated by reference.

Shell et al. disclose oral dosage forms of drugs by incorporating them into polymeric matrixes comprised of hydrophilic polymers that swell upon imbibition of water to a size which is large enough to promote retention of the dosage form in the stomach during the feed mode. Examples of hydrophilic polymers include cellulose polymers and their derivatives, microcrystalline cellulose and xanthan gum. The Office Action refers to Example 4 of Shell et al. which discloses metformin controlled release dosage forms with various polymers such as xanthan gum, HPMC, hydroxyethyl cellulose and polyethylene oxide. Magnesium stearate may be included in the various formulations. The Office Action also refers to Example 10, which

discloses a metformin dosage from comprising metformin, PEO, magnesium stearate and a coating comprised of HPMC.

However, Shell et al. do not disclose the inclusion of maltodextrin in the pharmaceutical composition.

The Office Action is citing Shell et al. for its teaching of the use of metformin as a drug.

It is respectfully submitted that even if combined in the manner suggested the combination does not overcome the deficiency referred to hereinabove or teach, disclose or suggest the present invention.

Shell et al. do not disclose the inclusion of maltodextrin in the pharmaceutical composition.

Thus, the combination would suggest that the maltodextrin is not blended together with the sustained release carrier, the drug and the water insoluble or partial water insoluble cellulose in the core in the pharmaceutical composition. According to Shah et al., the maltodextrin is in the immediate release formulation and not with the sustained release formulation, which is separate and distinct portion of the pharmaceutical composition. The sustained release formulation portion does not contain any maltodextrin. Thus, in Shah et al., there is no interaction between the maltodextrin and the water insoluble or partially water insoluble cellulose; they cannot, in combination, further control the release of the drug, unlike the claim of the present invention. Since Shell et al. do not include maltodextrin in their formulation, the combination cannot overcome the deficiency of Shah et al and thus cannot suggest that the maltodextrin and the water insoluble or partially water insoluble cellulose be present in the controlled release portion of the pharmaceutical composition and interact so that

together they can further control the release of the drug, as claimed. Therefore, this rejection is obviated; withdrawal thereof is respectfully requested.

Pursuant to the rejection of Claims 38, 40-47, 54-56, 59, 60, 63-66 and 71-73 under 35 U.S.C. § 103(a), the Office Action cites Seroff et al. and Shell et al.

Applicant reiterates its comments regarding Seroff et al., the contents of which are incorporated herein by reference, including the comments regarding Example 4B therein. Seroff et al in Example 4B refer to an internal compartment comprising a bilayered compressed core with a drug layer and a push layer, where the drug layer comprises, *inter alia*, roboxetine and maltodextrin and the push layer comprises polyethylene oxide, hydroxypropylmethylcellulose, which is water soluble and a barrier layer containing ethyl cellulose. Thus Seroff et al. do not disclose in Example 4B a water insoluble or partial water insoluble cellulose together as a homogenous mixture with the drug, the maltodextrin and the sustained release hydrophilic carrier. Further, Seroff et al. do not have the drug, and the maltodextrin, the water insoluble or partial water insoluble cellulose and the sustained release carrier all mixed together as homogenous so that they interact with one another. As a result, the maltodextrin, for example, cannot interact with the water insoluble or partially water insoluble portion to act in combination to further control the release of the drug. When the maltodextrin is a different layer, there is no interaction between it and the drug, the insoluble or partially insoluble cellulose and the hydrophilic sustained release carrier.

Shell et al. do not overcome this deficiency. The Office Action is citing Shell et al. for substituting the hydrophilic polymer for the sustained release polymer. However, this would mean a substitution of the cellulose ethers in the push layer with the hydrophilic polymer of Shell et al. indicated hereinabove. Thus, even if combined, maltodextrin and the water

insoluble or partially water insoluble cellulose are in different layers, and thus they are all not in one layer, e.g., the core. Thus, the combination does not teach, disclose or suggest that the maltodextrin is mixed with the sustained release carrier, the water insoluble or partial water insoluble cellulose and the drug in one layer, as claimed. But, more importantly, since Shell et al. do not include maltodextrin in their formulation, the combination cannot overcome the deficiency of Seroff et al and thus cannot suggest that the maltodextrin and the water insoluble or partially water insoluble cellulose be present in the controlled release portion of the pharmaceutical composition and interact so that together they can further control the release of the drug, as claimed. Therefore, this rejection is obviated; withdrawal thereof is respectfully requested.

Pursuant to the rejection of Claim 38, 40-48, 54-56, 59, 60, 63-73 the Office Action cites Seroff et al. and Shell et al. and Tobyn et al.

Applicant reiterates the comments hereinabove with respect to Seroff et al. and Shell et al., the contents of which are incorporated by reference.

The Office Action is citing Tobyn et al. for the alleged substitution or equivalence of SMCC for microcrystalline cellulose.

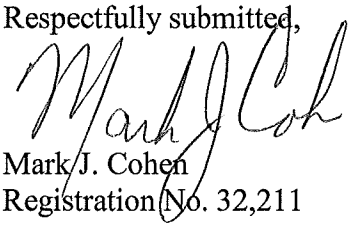
The arguments presented hereinabove regarding Seroff et al. and Shell et al. are applicable. Tobyn et al. do not address the inadequacies of Seroff et al. and Shell et al. It merely discloses that there is no discernable chemical or polymorphic difference between microcrystalline cellulose and silicified microcrystalline cellulose. Thus, Tobyn et al. do not address the deficiency of Shell et al. and Seroff et al. described hereinabove. The combination would at best suggest substituting silicified microcrystalline cellulose for microcrystalline cellulose. Accordingly, the combination would suggest a push layer containing soluble cellulose

ether, the barrier layer containing ethyl cellulose, and the drug layer containing the drug and maltodextrin. The combination of Seroff et al. and Shell et al. and Tobyn et al. do not teach, disclose or suggest a sustained release formulation wherein the drug, the sustained release hydrophilic carrier, maltodextrin and the water insoluble or partially water soluble cellulose are all part of a homogenous mixture and are not in discrete layers. Further, if combined, the cited document would not suggest that the water insoluble or partially water insoluble cellulose interact with one another to act in combination to further control the release of the drug, as claimed.

Accordingly, for the reasons provided, this rejection is overcome; withdrawal thereof is respectfully requested.

Thus, in view of the Amendment to the Claims and the Remarks, it is respectfully submitted that the present case is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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